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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/731,660 | 12/08/2000 | Haruhiko Kouhara | 038602/1023 | 1711 |

7590

11/03/2005

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Washington, DC 20007-5109

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| EXAMINER |
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HUTSON, RICHARD G

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,660

Applicant(s)

KOUHARA ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,6,11-13,20,21,23 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,11-13,20,21,23 is/are allowed.
- 6) ☒ Claim(s) 5,6 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of claims 30, 36 and 38, in the paper of 8/5/2005, is acknowledged. Claims 2, 5-6, 11-13 and 20, 21, 23 and 30-39 are at issue and are present for examination. Applicants arguments presented on 1/21/2005 and 8/5/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 30-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to claims 5, 6, and 30-39. In response to the previous office action applicants have amended claims 30, 36 and 38 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that claims 5, 6 and 30-39, as amended comply with the written description requirement, as these claims recite both structural and functional elements, specifically all of the claims recite structural elements related to SEQ ID NO: 1 and claim 36 is directed to a nucleic acid probe. Applicants

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continue to traverse this rejection on the basis that applicants have amended the claims to replace the term “comprising” with “consisting of”.

Applicants complete argument is acknowledged, however, continues to be found nonpersuasive for the reasons previously made of record. While applicants submit that all of the rejected claims recite both structural and functional language, this is insufficient to adequately describe the rejected claims. Applicants description would be helped by a showing of the structure to function “relationship” of the rejected claims, not merely a recitation of structure and function.

With respect to applicants statement that they have amended the claims to replace the term “comprising” with “consisting of”, this amendment remains in sufficient to define the claimed genus such that applicants description of the claimed genus is sufficient. Claim 36 remains drawn to a nucleic acid probe “**consisting** of a nucleic acid molecule that **encodes** an amino acid sequence **consisting** of a fragment of SEQ ID NO: 1 **consisting** at least 10 contiguous amino acids...” This claim remains open by virtue of the use of “encodes”.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 5, 6, 30-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a FRS2 polypeptide, wherein said FRS2 polypeptide has the amino acid sequence of SEQ ID NO: 1, does

not reasonably provide enablement for any nucleic acid encoding any FRS2 polypeptide wherein said FRS2 polypeptide merely comprises amino acid residues 1-10 of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to claims 5, 6, and 30-39. In response to the previous office action applicants have amended claims 30, 36 and 38 and traverse the rejection as it applies to the newly amended claims.

Applicants continue to traverse this rejection on the basis that the specification provides a function for a nucleic acid probe encoding a polypeptide comprising 10 contiguous amino acids of SEQ ID NO: 1 (i.e. 30 nucleotides) and applicants have amended the claims by replacing the term "comprising" with "consisting of".

Applicants complete argument is acknowledged, however found nonpersuasive for the reasons previously stated and repeated below.

As stated above, under the rejection based on a lack of written description, claim 36 continues to use open language based on the recitation of "encodes".

With respect to applicants argument that applicants specification provides a function for a nucleic acid probe encoding a polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO: 1, applicants are reminded that as a part of the enablement requirement applicants are required enable the claimed invention with respect to how to **make** and **use** the invention commensurate in scope with these claims and that a majority of the nucleic acids encompassed by the rejected claims will

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not be able to be used as such a “nucleic acid probe” by virtue of the remaining open language (see above discussion regarding “encodes”). If there is no associated function/activity of the claimed nucleic acid molecules, how have applicants enabled how **to use** such nucleic acids.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid encoding any polypeptide comprising a mere 10 contiguous amino acids of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

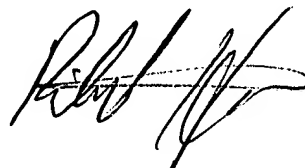
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a stylized flourish at the end.

rg
10/26/2005

**RICHARD HUTSON, PH.D.
PRIMARY EXAMINER**